

REMARKS

Applicant requests reconsideration of this application in view of the following remarks. No amendments are made to the claims. Claims 1, 4, 6, 8, 9, 11-17, 48 and 51-53 are pending.

Please withdraw the claim rejections under 35 USC §112, 1st and 2nd paragraphs

At pages 4 and 5 of the Office Action, the Examiner objects to at least claim 1 as not complying with the requirements of USC §112, 1st and 2nd paragraphs. Specifically, the Examiner asserts that changing the order of steps (b) and (c) in claim 1 provides a basis for these rejections and that it would be “unclear ... how one can insert a device into a solution (recited step c) prior to ‘providing’ said solution (recited in step b).”

Applicant respectfully traverses these rejections because Applicant submits that the language of claim 1 is clear and readily understood by one of ordinary skill in the art. In short, when claim 1 is read in a technically sensible manner and the words as used are interpreted as they are read by a skilled artisan, it is clear that the order of steps (b) and (c) may be reversed. Either a device is inserted into the container and then a solution is added, or the solution is added to the container and the device is inserted into the container containing the solution. A skilled artisan would readily understand that these steps may be reversed and that reciting these two alternative embodiments is not indefinite or not enabled.

Applicant submits that that a skilled artisan understands what is technically meant by the reversal of the order to steps (b) and (c) and would clearly be able to perform the two alternative orders of addition. Withdrawal of these rejections is requested.

Please withdraw the claim rejections under 35 USC §103

At pages 7-11 of the Office Action the Examiner rejects claims 1, 4, 6, 8, 11, 12, 16 and 17 as being unpatentable based on the combination of Song (WO 2005/016399) and Talalay (US 4,063,367). Specifically, the Examiner asserts that Song teaches all elements of at least claim 1, except for the isothermal drying step (d) which, however, is alleged to be reported by Talalay.

Applicant traverses this rejection for at least the reasons that Talalay does not report an isothermal drying step, there is no basis to combine Song with Talalay, and this combination

does not predict that a device may be coated according to the method now recited in the pending claims.

First, Talalay - in contrast to the Examiner's assertion - does not teach or suggest an isothermal drying and the drying method of Talalay cannot be subsumed under the description of isothermal drying as provided in the specification of the present application at page 20. Rather, Talalay reports that warm dried air with a temperature of approximately 65°C is applied (see column 3, lines 56-58) which is then dehumidified (see column 3, lines 49-60). Applicant submits that this high temperature is far beyond the temperature applied in the current isothermal drying. In fact, isothermal drying applies an ambient temperature of about 25°C (see the present specification at page 23, lines 20-22) in order to not inactivate the biologically active coating substance. Moreover, in an isothermal drying process the air is not dehumidified. Rather, the air is cooled down by means of an ice-cooled condenser (see the present specification at page 20, lines 6-11).

Further, Talalay reports that the air flows along the container with high velocity (see, e.g., claim 1 of Talalay). However, the high velocity applied in the drying method of Talalay would be counterproductive in the current claimed method, since it would disturb the homogenous coating of the coating substance.

Furthermore, Talalay reports that the air pressure is decreased after the drying process takes place:

In operation and assuming that a seal has been placed on and is magnetically held on sealing member 85, when a tray 18 is introduced onto plate 60 cylinder 68 is actuated to move assembly 70 and chamber member 77 down into the grooves 80 on plate 60 thus creating an air-tight chamber. A vacuum pump is then energized to produce a high vacuum on the order of about 500 microns in the chamber. This removes any residual moisture in the containers and also any airborne contaminants, as well as essentially eliminating oxygen from the containers. (see column 4, lines 50-60)

However, the isothermal drying according to the present invention is carried out under reduced pressure (see the present specification at page 20, line 12).

Finally, the result of the drying process of Talalay is a dried biologically active material adhered to the walls of the container:

The invention provides dry, positively sealed containers of biologically active material which is not friable and well adhered to the wall of the container in which it is dried. (see column 6, lines 45-48)

Applicant submits that this is clearly the opposite of what the present invention teaches and for what the claimed method provides: a biologically active material coated on a device (and not on the walls of the coating container).

All in all, Talalay does not teach or suggest isothermal drying and, what is more, applying the teaching of Talalay to the method of Song would - because of the reasons explained below - not lead to a predictable result.

Second, the Examiner does not provide sufficient reasoning as to why one of ordinary skill in the art should have modified the teaching of Song with the process taught by Talalay. Thus, the Examiner has not established a *prima facie* case of obviousness.

As previously explained in the response of January 27, 2010, there is no discussion within Song that the drying process using an oven is less than optimal or otherwise in need of improvement, and thus one of ordinary skill in the art would not be motivated to alter Song's drying process. Indeed, a mere statement, as set out in the Office Action, that the claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish a *prima facie* case of obviousness. Instead, there must be some articulated reasoning with some rational underpinning to support a conclusion that the pending claims are unpatentable. This prerequisite reasoning has not been provided by the Examiner.

Third, the mere fact that references are combined or modified does not render the claims unpatentable unless the coating substance results provided by the present invention would have been predictable to one of ordinary skill in the art.

In the present case, the coating substance result of the present invention is not predicted by combining the teaching of Song with that of Talalay. Song reports drying of a coated implant with an oven, while Talalay reports a method for drying a solid-liquid composite with the aim of dehydrating the composite in order to make it more stable. Thus, the method of Talalay is not suitable to dry a coated substance on a device.

In fact, Talalay is concerned with the dehydration of liquid-solid compositions which is reflected in claim 1 of Talalay, provided below:

Claim 1. A method of drying liquid from a liquid-solid composite in a round container comprising the step of directing a relatively high velocity stream of dry air over said container in a housing substantially parallel to the surface of the liquid in said container to create a vortex in said container and reduce the pressure in said container while maximizing the area of the exposed liquid to thereby evaporate the liquid from said container.

In particular, the method of Talalay provides that:

This invention relates to the dehydration of liquid-solid composites so that the resulting solid may be stored over a long shelf life. (see column 1, lines 7-9)

However, the device coated in accordance with the current claimed method is not dried for the purpose to store it over a long shelf life, it is dried to complete the coating of the device.

Talalay further reports that:

The invention is particularly adaptable to the dehydration of biologically active agents. (see column 1, lines 10-11)

However, the device coated in accordance with the present claimed method is not dried with the aim of dehydrating a biologically active ingredient. Rather, it is dried with the aim of removing volatile components of the coating substance solution.

In addition, the method of Talalay is based on the drawbacks of the prior art and thus Talalay aims at stabilizing biologically active materials, i.e., materials that contain moisture in order to increase their shelf life:

It is well known that biologically active materials are far more stable in dry form than they are in solution or a semi-dry state. For example, a biotic known as Cephalothin is considered stable for 24 months in dry powder form while it is only considered stable for 6 hours at room temperature in a suitably buffered solution. Even when refrigerated, such a solution is considered stable for only about 2 days. If elevated in temperature above room temperature to any significant degree, rapid deterioration of the solution takes place in terms, of loss of biological activity. Normal drying procedures such as subjecting a

solution to elevated temperature frequently accompanied by air circulation is unsuitable for the drying of these biologically active materials. (see column 1, lines 12-25)

In the claimed method of the present invention the liquid solution is evaporated by isothermal drying in order to gently dry it, thereby completing the homogenous distribution of the coating on the device. In stark contrast, Talalay aims at drying a liquid-solid composition.

An object of this invention is to provide a new method for drying liquid-solid composites. (see column 2, lines 8-9)

Thus, if one of ordinary skill in the art would have (hypothetically) applied the teaching of Talalay in the method of Song, the result would not have been predictable. Indeed, Song aims at drying a device coated with a desired substance in an oven, while Talalay aims at dehydrating a liquid-solid composite in order to make it more stable.

In sum, although Song and Talalay aim at drying “something,” they indeed dry this “something” for totally different purposes. Song aims at drying a device, i.e., remove a liquid (a solution) from the surface of a solid device, while Talalay removes a liquid contained in a solid liquid composite.

For at least the foregoing reasons, it was not predictable to one of ordinary skill in the art to modify the drying step of the method of Song with the drying method of Talalay.

Applicant requests that the rejection of the claims as being unpatentable over Song in view of Talalay be withdrawn.

Because of the same reasons as provided above and the inability of Talalay to overcome the noted deficiencies of Song, the combined teaching of Song, Talalay and Kohnert cannot render obvious the claimed method of the present invention, as asserted by the Examiner at pages 11-13 of the Office Action.

Likewise, the combination of Song, Talalay and Lee cannot render obvious the claimed method of the present invention as asserted by the Examiner at pages 13 and 15 of the Office Action.

Finally, the combination of Song, Talalay and Gao cannot render obvious the claimed method of the present invention as asserted by the Examiner on page 15 of the Office Action.

In conclusion, all of the pending claims in this application should now be in condition for allowance. A prompt notice to that effect is respectfully solicited. If there are any remaining questions, the Examiner is requested to contact the undersigned at the number listed below.

Respectfully submitted,

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